



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 05-957-G; EX03-075C-US)

In re Application of:	)	
	)	
Gregory D. Plowman et al.	)	
	)	Art Unit: N/A
Serial No.: 10/532,547	)	
	)	Examiner: N/A
Filed: April 22, 2005	)	
	)	Conf. No. 6196
For: MBM's As Modifiers of Branching	)	
Morphogenesis and Methods of Use	)	

SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. These references are also listed on the enclosed PTO Forms SB/08a and SB/08b. Also, enclosed is a copy of the International Search Report in which the references listed below were cited during the prosecution of a corresponding PCT application.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative relevance between references, whether cited in this or prior statements. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

This Information Disclosure Statement is being filed:

- ☒ within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. § 1.97 (b)
- ☐ after three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or **after** the mailing date of a first Office Action on the merits, but **before** the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c):
- ☐ the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below)

**OR**

- ☐ the fee of \$180.00 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).
- ☐ **after** a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" and "Method of Payment of Fees" below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

#### CERTIFICATION

- ☒ The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**FEES**

- ☒ No fee is owed by the applicant(s).  
☐ The IDS Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

**METHOD OF PAYMENT OF FEES**

- ☐ Attached is a check in the amount of \$180.00

**Foreign References**

1. International Application No. WO 02/077033, published October 3, 2002 (McKenzie et al.).
2. International Application No. WO 02/059620, published August 1, 2002 (Bianco et al.).

**Article References**

3. ATABEY et al.: "Potent blockade of hepatocyte growth factor-stimulated cell motility, matrix-invasion and branching morphogenesis by antagonists of Grb2 Src homology 2 domain interactions," The Journal of Biological Chemistry, April 27, 2001; Vol. 276, No. 17, pages 14308-14314; ISSN: 021-9258.
4. LALANI, et al.: "Trefol factor-2, human spasmolytic polypeptide, promotes branching morphogenesis in MCF-7 cells," Laboratory Investigations, May 1999, Vol. 79, pages 537-546.
5. KOOCHKEPOUR et al.: "The von-Hippel-Lindau tumor suppressor gene inhibits hepatocyte growth factor/scatter factor-induced invasion and branching morphogenesis in renal carcinoma cells," Molecular and Cellular Biology, September 1999, Vol. 19, pages 5902-5912.
6. PISCIONE et al.: "BMP-2 and OP-1 exert direct and opposite effects on renal branching morphogenesis," American Journal of Physiology, December 1997, Vol. 273, No. 6, part 2, pages F961-F975.
7. PETERS et al.: "Targeted expression of a dominant negative FGF receptor blocks branching morphogenesis and epithelial differentiation of the mouse lung," EMBO Journal, July 15, 1994, Vol. 13, pages 3296-3301.
8. SERRA et al.: "TGF-beta inhibits branching morphogenesis and N-myc expression in lung bud organ-cultures," Development, August 1994, Vol. 120, pages 2153-2161.

9. SCHUGER et al.: "Amphiregulin in lung branching morphogenesis: interaction with heparan sulfate proteoglycan modulates cell proliferation," Development, June 1996, Vol. 122, pages 1759-1767.
10. CANCELLA et al.: "Regulation of prostate branching morphogenesis by activin A and follistatin," Developmental Biology, September 1, 2001, Vol. 237, page 145-158.
11. MARKER et al.: "Fucosyltransferase and H-type complex carbohydrates modulate epithelial cell proliferation during prostatic branching morphogenesis," Developmental Biology, May 1, 2001, Vol. 233, pages 95-108.
12. BARROS et al.: "Differential tubulogenic and branching morphogenetic activities of growth factors: implications for epithelial tissue development," Proceeding of the National Academy of Sciences of the United States, May 9, 1995, Vol. 92, pages 4412-4416.
13. Adamson et al.: "Cripto: a tumor growth factor and more," Journal of Cellular Physiology, March 2002, Vol. 190, pages 267-278.
14. SALOMAN et al.: "The EGF-CFC family: novel epidermal growth factor-related proteins in development and cancer," Endocrine-Related Cancer, December 2000, Vol. 7, pages 199-226.
15. RADVANYI et al.: "Pancreatic beta cells cultured from individual preneoplastic foci in a multistage tumorigenesis pathway, a potentially general technique for isolating physiologically representative cell lines," Molecular and Cellular Biology, July 1993, Vol. 13, pages 4223-4232.

In accordance with MPEP Sections 609 and 707.05(b), it is requested the document cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Respectfully Submitted,

*Sherri L. Oslick*

Sherri L. Oslick, Ph.D.

Reg. No. 52,087

*Dec. 13, 2006*

Substitute for form 1449B/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **2**

of

**4**

Application Number

**Complete if Known**

**10/532547**

Filing Date

**April 22, 2005**

First Named Inventor

**Gregory D. Plowman**

Art Unit

**N/A**

Examiner Name

**N/A**

Attorney Docket Number

**105-957-G**

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	7 <sup>2</sup>
	B3	ATABEY et al.: "Potent blockade of hepatocyte growth factor-stimulated cell motility, matrix-invasion and branching morphogenesis by antagonists of Grb2 Src homology 2 domain interactions," The Journal of Biological Chemistry, April 27, 2001; Vol. 276, No. 17, pages 14308-14314; ISSN: 021-9258.	
	B4	LALANI, et al.: "Trefol factor-2, human spasmodic polypeptide, promotes branching morphogenesis in MCF-7 cells," Laboratory Investigations, May 1999, Vol. 79, pages 537-546.	
	B5	KOOCHKEPOUR et al.: "The von-Hippel-Lindau tumor suppressor gene inhibits hepatocyte growth factor/scatter factor-induced invasion and branching morphogenesis in renal carcinoma cells," Molecular and Cellular Biology, September 1999, Vol. 19, pages 5902-5912.	
	B6	PISCIONE et al.: "BMP-2 and OP-1 exert direct and opposite effects on renal branching morphogenesis," American Journal of Physiology, December 1997, Vol. 273, No. 6, part 2, pages F961-F975.	
	B7	PETERS et al.: "Targeted expression of a dominant negative FGF receptor blocks branching morphogenesis and epithelial differentiation of the mouse lung," EMBO Journal, July 15, 1994, Vol. 13, pages 3296-3301.	
	B8	SERRA et al.: "TGF-beta inhibits branching morphogenesis and N-myc expression in lung bud organ-cultures," Development, August 1994, Vol. 120, pages 2153-2161.	
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	B10	CANCILLA et al.: "Regulation of prostate branching morphogenesis by activin A and follistatin," Developmental Biology, September 1, 2001, Vol. 237, page 145-158.	
	B11	MARKER et al.: "Fucosyltransferase and H-type complex carbohydrates modulate epithelial cell proliferation during prostatic branching morphogenesis," Developmental Biology, May 1, 2001, Vol. 233, pages 95-108.	
	B12	BARROS et al.: "Differential tubulogenic and branching morphogenetic activities of growth factors: implications for epithelial tissue development," Proceeding of the National Academy of Sciences of the United States, May 9, 1995, Vol. 92, pages 4412-4416.	

Examiner  
Signature

/Karen A. Canella, Ph.D./

Date  
Considered

**12/22/2008**

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). \* Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

